# General

## Guideline Title

Dexamethasone intravitreal implant for treating diabetic macular oedema.

## Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Dexamethasone intravitreal implant for treating diabetic macular oedema. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Jul 22. 65 p. (Technology appraisal guidance; no. 349).

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Recommendations

## Major Recommendations

Dexamethasone intravitreal implant is recommended as an option for treating diabetic macular oedema only if:

- The implant is to be used in an eye with an intraocular (pseudophakic) lens and
- The diabetic macular oedema does not respond to non-corticosteroid treatment, or such treatment is unsuitable

People whose treatment with dexamethasone intravitreal implant was started within the National Health Service (NHS) before this guidance was published, but is not recommended for them by the National Institute for Health and Care Excellence (NICE) in this guidance, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.

## Clinical Algorithm(s)

None provided

# Scope

## Disease/Condition(s)

Diabetic macular oedema

## Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

## Clinical Specialty

Endocrinology

Geriatrics

Ophthalmology

Optometry

## Intended Users

Advanced Practice Nurses

Nurses

Optometrists

Physician Assistants

Physicians

## Guideline Objective(s)

To assess the clinical effectiveness and cost-effectiveness of dexamethasone intravitreal implant for treating diabetic macular oedema

## Target Population

Adult patients with visual impairment due to diabetic macular oedema

## Interventions and Practices Considered

Dexamethasone intravitreal implant

## Major Outcomes Considered

- Clinical effectiveness
  - Best corrected visual acuity (BCVA) change from baseline
  - BCVA improvement
  - BCVA worsening
  - Contrast sensitivity
  - Anatomical change from baseline
  - Safety and tolerability
  - Health-related quality of life
- Cost-effectiveness

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

## Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by BMJ Technology Assessment Group (BMJ-TAG) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of the Methods of Reviews(s)

*Description and Critique of Company's Search Strategy*

The company reported that they conducted the searches to identify randomised controlled trials (RCTs) for the systematic review (SR) on 13th February 2014 and then updated the searches on 17th July 2014. The searches comprised of terms for diabetes AND macular oedema AND the interventions of interest (i.e., dexamethasone, laser photocoagulation, bevacizumab, ranibizumab and fluocinolone acetonide). In addition RCT and SR search filters were applied in the searches of MEDLINE, EMBASE and CINAHL. The ERG notes that the intervention search terms included triamcinolone acetonide and aflibercept although these were not specified as interventions of interest in the final scope issued by NICE or the company SR. The ERG considers the omission of both of these from the company's SR results to be appropriate as neither drug has European Unit (EU) marketing authorisation for use in diabetic macular oedema (DMO). In addition, clinical experts informed the ERG that neither triamcinolone acetonide nor aflibercept are currently routinely used in the UK for the management of DMO.

The following electronic databases were searched:

- Medline and Medline in Process & Other Non-Indexed citations - 1948–present
- EMBASE - 1974–July 16
- Cochrane Database of Systematic Reviews (CDSR) - 1996–present
- Cochrane Central Register of Controlled Trials (CENTRAL) - 1898–present
- Health Technology Assessment Database (HTA) - 1995–present
- Database of Abstracts of Review of Effects (DARE) - 1995–present
- Cumulative Index to Nursing and Allied Health Literature (CINAHL) - 1982–present

See Table 7 in the ERG report for details.

In addition, it is reported in the company submission (CS) that the reference lists of SRs, meta-analyses and clinical guidelines identified during the searches were hand-searched to identify any further relevant studies. The unpublished data on file held by the manufacturer were also reviewed to identify further studies and data of relevance for the SR.

The company undertook searches of clinicaltrials.gov and selected relevant annual conference proceedings for the period of 2012-2013 or 2012-2014 for the purpose of identifying relevant on-going research.

See Section 4.1.1 of the ERG report for the list of conference proceedings searched.

In addition to the database searches for RCTs, the company conducted further database searches to identify non-RCT data to assist in addressing the review question. These searches were conducted on 18th July 2014 and were carried out in the same electronic databases as the searches for RCT evidence. The search terms used for the non-RCT searches comprised of terms for diabetes AND macular oedema AND dexamethasone.

No restrictions were placed on date or study design. Further details on the search strategies used by the company for both the RCT and non-RCT evidence are presented in Appendix 9.1 of the ERG report (see the "Availability of Companion Documents" field).

*Inclusion/Exclusion Criteria Used in Study Selection*

The company reported that two levels of study screening were conducted using the inclusion and exclusion criteria for the SR. The two levels of screening were conducted independently by two reviewers. Level 1 screening comprised of reviewing the abstracts of each identified reference. All references identified at level 1 as of potential relevance were retrieved in full text and the full texts were reviewed as part of the level 2 screening. It is reported in the CS that discrepancies between the two reviewers with regard to inclusion or exclusion of an article were resolved by a third reviewer. The final set of studies for the SR comprised of those articles that met all of the inclusion criteria and none of the exclusion criteria.

Eligibility Criteria Applied to Systematic Search Results Identifying the Clinical Evidence Base of RCTs

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| Population<br>• Adult<br>• Unilateral or bilateral DMO associated to DM<br>• Pre-treated or treatment-naïve | Population<br>• Paediatric<br>• Diabetic retinopathy patients without associated DMO<br>• Macular oedema not associated to DM |
| Interventions (one or more of the following)<br>• Intravitreal dexamethasone 700 µg<br>• Laser photocoagulation (ETDRS guidelines)<br>• Intravitreal bevacizumab 1.25 mg PRN<br>• Intravitreal ranibizumab 0.5 mg PRN<br>• Intravitreal fluocinolone acetonide 0.2 µg<br>• Monotherapy or combination pharmaceutical/laser therapy | Interventions<br>• Local corticosteroids<br>• Local anti-VEGFs<br>• Dosing regimens outside of UK licence terms/clinical practice |
| Comparators (one or more of the following)<br>• Active therapy<br>• Placebo<br>• Sham treatment<br>• No treatment | |
| Outcomes (one or more of the following)<br>• BCVA change from baseline<br>• BCVA improvement<br>• BCVA worsening<br>• Contrast sensitivity<br>• Anatomical change from baseline<br>• Safety and tolerability<br>• Health related quality of life | Outcomes<br>• Non-vision or anatomical related efficacy measures |
| Study Design<br>• RCTs | Study Design<br>• Prospective non-RCTs<br>• Single arm trials<br>• Observational studies |
| Study Duration<br>• ≥6 months (24 weeks) | Study Duration<br>• <6 months (24 weeks) |

| Inclusion Criteria | Exclusion Criteria |
| --- | --- |

Abbreviations used in the table: BCVA, best corrected visual acuity; DM, diabetes mellitus; DMO, diabetic macular oedema; ETDRS, Early Treatment of Diabetic Retinopathy Study; PRN, as needed; RCT, randomised controlled trial; UK, United Kingdom; VEGF, vascular endothelial growth factor.

The inclusion and exclusion criteria for non-RCT evidence had more restrictions than the RCT evidence review. The key differences were that the non-RCT evidence review limited the interventions to intravitreal dexamethasone 700µg monotherapy or combination with laser therapy. In addition, the study design restrictions for the non-RCT evidence limited inclusion to prospective non-RCTs, single arm trials and observational studies containing more than five patients with DMO.

See Section 4.1.2 of the ERG report for additional information on inclusion/exclusion criteria.

*Details of RCTs Included in the Review of Clinical Effectiveness*

The company reported that combining the results of the original search and updated database search with the findings from the conference proceeding searches and other searches resulted in the identification of 4,441 potentially relevant citations.

These 4,441 citations comprised of 2,541 from the database searches, 1,891 from the conference proceeding searches and 9 from other sources.

After deduplication, there were a total of 3,400 articles which were assessed at level 1 (abstract screening) and 2,728 of them were excluded from further review. The remaining 675 citations were reviewed at level 2 as full text articles where available. Level 2 screening resulted in the identification of 65 RCTs in 90 publications for inclusion in the SR. Reasons for exclusion included non-RCT study design (n = 163), post-hoc/pooled analysis (n = 46), study duration <24 weeks (n = 34), abstract only with not enough detail to assess study in full (n = 10), article unavailable (n = 5). Of the 65 RCTs meeting the eligibility criteria, 6 investigated the clinical efficacy and safety of dexamethasone 700 µg (see Table 9 in the ERG report). The remaining 59 RCTs provided data on the comparators specified in the decision problem and thus contribute only indirect evidence.

*Details of Non-RCTs Included in the Review of Clinical Effectiveness*

The company reported that the non-RCT searches of electronic databases identified a total of 396 potentially relevant articles which after removal of duplicates left 313 articles for review. In addition, there were 103 potentially relevant citations identified through the searches of the conference proceedings and one further citation (abstract presented at conference, 2010) obtained from the company in house archives.

A total of 417 articles were reviewed at level 1 (abstract) screening with 386 of them excluded from further review. Level 2 screening (full text where available) thus involved review of 31 articles of which 10 studies in 11 publications met the inclusion criteria for the review of non-RCT evidence (see Table 10 in the ERG report). The company reported that of the 10 studies, only 9 reported data of relevance to the populations for which dexamethasone has EU marketing authorisation (detailed in Table 10 of the ERG report).

The results of the 9 non-RCT studies were summarised in a narrative review in the CS. The ERG considers the company's use of the non-RCT evidence to be appropriate. The ERG does not consider the non-RCT evidence to add additional information to the RCT evidence presented in the CS to address the decision problem, and thus the ERG does not discuss the findings of the non-RCT studies further in this report. However, the results for the non-RCT review as reported in the CS are presented in Appendix 9.4 and 9.5 of the ERG report for completeness.

Cost-effectiveness

ERG Comment on Company's Review of Cost-effectiveness Evidence

The company carried out a systematic review of the economic literature to identify cost-effectiveness studies of therapies used in the treatment of vision impairment due to DMO. The search was carried out in February 2014 and updated in July 2014. Searches were performed in Medline and Medline In-Process and other non-indexed citations, EMBASE, HTA, National Health Service Economic Evaluation Database (NHS EED), DARE, CINAHL, and EconLit.

Search terms captured the condition of interest (DMO), a range of interventions (dexamethasone, aflibercept, bevacizumab, ranibizumab, triamcinolone acetonide, fluocinolone acetonide and laser photocoagulation) and used filters for economic evaluation studies based on Scottish Intercollegiate Guidelines Network (SIGN) recommendations. No date or language limits were applied. Relevant NICE guidance was identified and included within the description of identified studies. Further details of the search strategy are provided in the company submission. All search strategies developed by the company for identification of relevant economic evidence, data on health related quality of life (HRQL) and resource use and costs are presented in Appendix 9.9 of the ERG report.

Studies were included in the review if they were a cost-effectiveness analysis evaluating a treatment for the management of vision impairment due to

DMO. Studies were excluded if they were not a cost-effectiveness analysis, they were a cost-effectiveness analysis in an indication other than DMO or they were a cost-effectiveness analysis in DMO but did not evaluate a treatment for the management of DMO (e.g., diagnostic testing for DMO). Studies were also excluded if they met the inclusion criteria but were available as an abstract only, as this was deemed to be insufficient evidence for inclusion in the review.

After removing duplicates, the company identified a total of 202 citations in the initial search and nine citations in the update. Following review of these citations, the company identified seven relevant studies, and through an additional search, two relevant NICE technology appraisals. The quality assessment for each study as well as methods and results of all studies were provided in the company submission.

## Number of Source Documents

Clinical Effectiveness

- Six randomised controlled trials (RCTs) were included in the review.
- Ten additional non-RCTs in 11 publications met the inclusion criteria.

Cost-effectiveness

- Seven articles were included in the review.
- Two relevant National Institute for Health and Care Excellence (NICE) appraisals were also identified through additional searches and were included in the description of identified studies, giving a total of nine identified studies of relevance.
- The manufacturer submitted an economic model.

## Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

## Rating Scheme for the Strength of the Evidence

Not applicable

## Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by BMJ Technology Assessment Group (BMJ-TAG) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of the Methods of Review(s)

*Critique of Data Extraction*

The company reported that the data extraction of the included trials was conducted by one reviewer using a pre-defined data extraction table. A second reviewer then verified the extracted data. The pre-defined data extraction table collected data on the basic characteristics of each selected study and the study results. The ERG considers the company’s data extraction strategy to be acceptable.

*Quality Assessment*

The company conducted a quality assessment for the trials included in the systematic review using criteria similar to the Cochrane risk of bias tool. A summary of the company's quality assessment for the six key trials presented within the company submission (CS) are presented in Table 11 of the ERG report with the full quality assessment for each randomised controlled trial (RCT) presented in Appendix 9.3 of the ERG report.

The ERG considers the six dexamethasone RCTs to be of reasonable quality with the main areas of concern relating to the absence of participant blinding in several of the trials and the relatively high discontinuation rates in the MEAD studies. In general, the ERG agrees with the company's overall quality assessment for each of the six trials.

*Evidence Synthesis*

The company reports the data separately for each of the six dexamethasone trials in the CS. In addition, the data from the two MEAD studies are presented as a pooled analysis. In response to clarification, the company also provided data of the MEAD studies from a standard pair wise meta-analysis.

In terms of the comparison of dexamethasone with the other comparators of interest specified in the decision problem, the company reports results from a network meta-analysis.

See Section 4 of the ERG report for more information on clinical effectiveness analysis.

Cost-effectiveness

Model Structure

The company's *de novo* model comprises a cohort Markov model that follows patients with diabetic macular oedema (DMO) over a 15-year time horizon and models costs and quality-adjusted life-years (QALYs) associated with treatment of DMO and subsequent changes in patients' best corrected visual acuity (BCVA). The model follows both eyes of each patient; BCVA changes in each eye are modelled independently. Treatment may be modelled in both eyes (bilateral DMO) or in either the better-seeing eye (BSE) or worse-seeing eye (WSE) (unilateral DMO). Patients within the cohort who are affected unilaterally at baseline may develop DMO in their second eye, termed fellow eye involvement (FEI) and move to bilateral treatment. The BSE and WSE of each patient are defined at baseline and fixed throughout the time horizon. As illustrated in Figure 29 of the ERG report, the Markov model consists of 6 visual acuity health states of 10-letter increments each, except the two extreme states, i.e., the mildest and the most severe; the definition of each health state is shown in Table 46 of the ERG report. Each eye with DMO may transition between the 6 BCVA states every 3 months, which is the cycle length of the model. In each 3-month cycle the eye may move up (improved vision) or down (worsened vision) by a maximum of one BCVA state, or the eye may remain in the same visual acuity health state (stable vision). Treatment for DMO influences the probability of transitioning between the BCVA states. Eyes without DMO are assumed to retain constant vision. All patients are at risk of death throughout the model time horizon. A half-cycle correction has been applied in the model.

The model assumes a maximum duration of treatment of 3 years in the base case. At any time during treatment patients within the cohort may discontinue from treatment for one of two independent reasons:

- Lack (or loss) of efficacy of treatment
- Adverse events and other non-efficacy related reasons (e.g., withdrawal of consent, lost to follow-up, protocol violation, personal reasons, etc.)

Discontinuation from treatment was modelled to reflect the high discontinuation rates that were observed within the MEAD trials (where 22.5% of patients in the pooled dexamethasone arms discontinued from the study due to adverse events and other non-efficacy related reasons, 4.3% discontinued due to lack or loss of efficacy of treatment and 9.8% were censored due to receipt of an off-protocol treatment).

The model also considered five key adverse events of interest that may require medical or surgical intervention, comprising cataract, raised intraocular pressure (IOP), retinal detachment, endophthalmitis and vitreous haemorrhage.

Visual acuity health states were based on a 10-letter change in BCVA on the ETDRS eye chart because, according to the company, this 10-letter change is often used as a measure of visual acuity in clinical trials of interventions for DMO.

The 3-month cycle length of the Markov model was selected to be consistent with the visit schedule in the MEAD trials, which are the main source of efficacy and resource use data for dexamethasone.

See Sections 5 and 6 of the ERG report for additional information on the company's cost-effectiveness analysis.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the Appraisal Consultation Document (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the Final Appraisal Determination (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

## Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

Summary of Appraisal Committee's Key Conclusions

Availability and Nature of Evidence

The Committee concluded that it had been presented with cost-effectiveness estimates for dexamethasone intravitreal implant in all necessary sub-populations to inform its decision-making.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

The Committee acknowledged the Evidence Review Group's (ERG's) concerns about several factors that could have biased the results, including

modelling transitions for each eye independently, 'normalising' the transition probabilities in the model to sum them to 1 and assuming that the relative effect of dexamethasone intravitreal implant compared with sham procedure was stable for 3 years. The Committee concluded that these assumptions reflected neither the natural course of the disease nor the observed clinical trial data, and that this increased the uncertainty of the results of the model.

The Committee considered the transition probabilities used for treatment discontinuation or censoring. It was not persuaded that adopting the last observed transition before discontinuation to inform the model cycles after discontinuation was plausible, as assumed in the company's new analyses. The Committee concluded that the company's original transition probability matrices according to disease natural history were less inappropriate for using in its decision-making than those in the company's new evidence submission.

Incorporation of Health-related Quality-of-Life Benefits and Utility Values. Have Any Potential Significant and Substantial Health-related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

The Committee noted that the utility values used in the company's model were based on trial data. It acknowledged that the company's approach to inclusion of utility values in the model had some limitations, but so too did the published utility values available. On balance, the Committee concluded that neither approach was ideal, but it agreed that the company's utility values were suitable to inform its decision-making, despite these limitations. However, it also concluded that neither approach was ideal and that both had shortcomings that inhibited the accurate estimation of the cost effectiveness of dexamethasone intravitreal implant for diabetic macular oedema (DMO).

Are There Specific Groups of People for Whom the Technology Is Particularly Cost Effective?

Not applicable

What Are the Key Drivers of Cost-effectiveness?

For people with diabetic macular oedema that has not responded adequately to non-corticosteroid therapy or for whom such treatment is unsuitable, the key driver of cost effectiveness in the model is the cost of residential care used for people with severe vision loss.

Most Likely Cost-effectiveness Estimate (Given as an Incremental Cost-effectiveness Ratio [ICER])

For people with a pseudophakic lens with central retinal thickness (CRT) of 400 μm or more, the Committee concluded that if the confidential patient access scheme for ranibizumab was included, it did not recommend dexamethasone intravitreal implant because its lower quality-adjusted life year (QALY) gain with a marginal difference in costs was not a cost-effective use of National Health Service (NHS) resources compared with ranibizumab.

For people with a pseudophakic lens with CRT less than 400 μm, the Committee noted that dexamethasone intravitreal implant was dominated by laser photocoagulation therapy and bevacizumab.

For people without a pseudophakic lens with diabetic macular oedema that is unsuitable for or insufficiently responsive to non-corticosteroid therapy, the Committee considered that the true value of the ICER would be greater than the ERG's new exploratory base-case ICER of £127,645 per QALY gained.

For people with a pseudophakic lens with diabetic macular oedema that is unsuitable for or insufficiently responsive to non-corticosteroid therapy the Committee noted that, when the exact discount agreed in the patient access scheme for fluocinolone acetonide intravitreal implant was taken into account, there was little difference in the total costs and total QALYs of fluocinolone acetonide intravitreal implant and dexamethasone intravitreal implant. Therefore, it considered that the cost effectiveness of dexamethasone intravitreal implant is likely to be similar to fluocinolone acetonide intravitreal implant.

## Method of Guideline Validation

External Peer Review

## Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination (FAD).

- Manufacturer/sponsors

- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence submitted by the manufacturer of dexamethasone intravitreal implant and a review of this submission by the Evidence Review Group (ERG). The main clinical effectiveness evidence came from 6 randomised controlled trials (RCTs). For cost-effectiveness, the Appraisal Committee considered an economic model submitted by the manufacturer.

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

Appropriate use of dexamethasone intravitreal implant for treating diabetic macular oedema

## Potential Harms

The summary of product characteristics includes the following adverse events as common or very common for dexamethasone intravitreal implant: headache, increased intraocular pressure, cataract and conjunctival haemorrhage.
The summary of product characteristics states that patients should be monitored following an injection of dexamethasone intravitreal implant.

For full details of adverse reactions see the summary of product characteristics.

# Contraindications

## Contraindications

For full details of contraindications, see the summary of product characteristics.

# Qualifying Statements

## Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

# Implementation of the Guideline

## Description of Implementation Strategy

- Section 7(6) of the National Institute for Health and Care Excellence (NICE) (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, National Health Services (NHS) England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.
- The Welsh Assembly Minister for Health and Social Services has issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 3 months of the guidance being published.
- When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraph above. This means that, if a patient has diabetic macular oedema and the doctor responsible for their care thinks that dexamethasone intravitreal implant is the right treatment, it should be available for use, in line with NICE's recommendations.
- NICE has developed tools to help organisations put this guidance into practice (listed below).
    - Costing template and report to estimate the national and local savings and costs associated with implementation

## Implementation Tools

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Living with Illness

## IOM Domain

Effectiveness

Patient-centeredness

# Identifying Information and Availability

## Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Dexamethasone intravitreal implant for treating diabetic macular oedema. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Jul 22. 65 p. (Technology appraisal guidance; no. 349).

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2015 Jul 22

## Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

## Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

## Guideline Committee

Appraisal Committee

## Composition of Group That Authored the Guideline

*Committee Members*: Professor Andrew Stevens (*Chair of Appraisal Committee C*), Professor of Public Health, University of Birmingham; Professor Eugene Milne (*Vice Chair of Appraisal Committee C*), Director of Public Health, City of Newcastle upon Tyne; Dr David Black, Medical Director, NHS South Yorkshire and Bassetlaw; David Chandler, Lay member; Professor Peter Crome, Honorary Professor, Dept of Primary Care and Population Health, University College London; Gail Coster, Advanced Practice Sonographer, Mid Yorkshire Hospitals NHS Trust; Professor Rachel A Elliott, Lord Trent Professor of Medicines and Health, University of Nottingham; Professor Wasim Hanif, Professor in Diabetes and Endocrinology, University Hospital Birmingham; Dr Alan Haycox, Reader in Health Economics, University of Liverpool Management School; Emily Lam, Lay member; Dr Nigel Langford, Consultant in Clinical Pharmacology and Therapeutics and Acute Physician, Leicester Royal Infirmary; Dr Allyson Lipp, Principal Lecturer, University of South Wales; Dr Claire McKenna, Research Fellow in Health Economics, University of York; Dr Patrick McKiernan, Consultant Pediatrician, Birmingham Children's Hospital; Dr Andrea Manca, Health Economist and Senior Research Fellow, University of York; Dr Suzanne Martin, Reader in Health Sciences; Dr Iain Miller, Founder & CEO, Health Strategies Group; Dr Paul Miller, Director, Payer Evidence, Astrazeneca UK Ltd; Professor Stephen O'Brien, Professor of Haematology, Newcastle University; Professor Peter Selby, Consultant Physician, Central Manchester University Hospitals NHS Foundation Trust; Professor Matt Stevenson, Technical Director, School of Health and Related Research, University of Sheffield; Professor Robert Walton, Clinical Professor of Primary Medical Care, Barts and The London School of Medicine & Dentistry; Dr Judith Wardle, Lay member

## Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Available from the National Institute for Health and Care Excellence (NICE) Web site .

## Availability of Companion Documents

The following are available:

- Dexamethasone intravitreal implant for treating diabetic macular oedema. Costing report. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Jul. 14 p. (Technology appraisal guidance; no. 349). Available from the National Institute for Health and Care Excellence (NICE) Web site .
- Dexamethasone intravitreal implant for treating diabetic macular oedema. Costing template. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Jul. (Technology appraisal guidance; no. 349). Available from the NICE Web site .
- Edwards SJ, Wakefield V, Mavranezouli I, Karner C, Marceniuk G, Azuara-Blanco A. Dexamethasone intravitreal implant for diabetic macular oedema: a single technology appraisal. London (UK): BMJ-TAG; 2014 Oct. 452 p. Available from the NICE Web site .
- Edwards SJ, Wakefield V, Mavranezouli I, Karner C, Marceniuk G, Azuara-Blanco A. Dexamethasone intravitreal implant for diabetic macular oedema: a single technology appraisal. Erratum. London (UK): BMJ-TAG; 2014 Oct. 42 p. Available from the NICE Web site .

## Patient Resources

The following is available:

- Dexamethasone intravitreal implant for treating diabetic macular oedema. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Jul. 3 p. (Technology appraisal guidance; no. 349). Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download in ePub and eBook formats from the NICE Web site .

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